

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the results of scaphoid waist fracture fixation using screws and screws with pins in acute scaphoid waist fractures

Protocol summary

Study aim

1. Comparison of scaphoid waist fracture fixation using a screw alone versus screw combined with pin fixation in acute scaphoid waist fractures based on the degree of functional improvement according to the MAYO questionnaire. 2. Comparison of the two groups in terms of pain severity. 3. Comparison of the two groups in terms of wrist range of motion in flexion and extension. 4. Comparison of the two groups in terms of fracture union rate. 5. Comparison of the two groups in terms of the scapholunate angle on lateral radiographs.

Design

randomized, single-blind, controlled clinical trial with parallel group conducted on 30 patients. Randomization was performed using SPSS software.

Settings and conduct

The study will be conducted at Besat Hospital in Hamadan. radiographs will be obtained at 1, 3, and 6 months after surgery, and the patients will be evaluated based on the study variables.

Participants/Inclusion and exclusion criteria

Inclusion criteria: provision of informed consent Exclusion criteria: Refusal to participate in the study, Loss to follow-up

Intervention groups

In the screw group (control), first, two 1-mm pins will be inserted under C-arm guidance from the volar to dorsal direction or vice versa, and from distal to proximal. Then, one screw will be inserted from distal to proximal. After that, the pins will be removed and a cast will be applied. In the screw-and-pin group (case), first, two pins will be inserted from distal to proximal and from volar to dorsal or vice versa toward the center of the scaphoid. Afterward, a screw will be inserted along the same axis, based on the size of the inserted and measured pin, and fixation will be achieved. The postoperative cast will be removed after approximately one month.

Main outcome variables

Functional improvement, pain severity, wrist range of

motion, fracture union rate, and the scapholunate angle on lateral radiographs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260423069141N1**

Registration date: **2026-07-19, 1405/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-19, 1405/04/28**

Update count: **0**

Registration date

2026-07-19, 1405/04/28

Registrant information

Name

Mohamad Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the results of scaphoid waist fracture fixation using screws and screws with pins in acute scaphoid waist fractures

Public title

Comparing scaphoid waist fracture fixation using screws and screws with pins

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmed scaphoid waist fracture

Exclusion criteria:

Presence of an associated wrist fracture
Chronic fracture
Fracture associated with ligament injury and perilunate injury
Need for open surgery (open surgical procedure)
Presence of SNAC signs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be used in this study. In this method, each patient will have an equal probability of being assigned to one of the two treatment groups, and patient allocation will be performed independently of the allocation of other participants. The unit of randomization in this study is individual randomization, meaning that each patient will be independently assigned to one of the two treatment groups. Stratified randomization will not be used in this study because the primary objective is to compare the overall outcomes of the two treatment methods, and no specific variable has been considered for stratification. The random allocation sequence will be generated using a random number table/statistical software. Initially, a random sequence for the entire sample size will be generated using statistical software (such as SPSS or Random Allocation Software), so that each patient will be randomly assigned to either the "screw fixation" group or the "screw plus pin fixation" group. The allocation result for each number will then be written on a separate sheet and placed inside an opaque envelope. The envelopes will be sequentially numbered. To prevent selection bias, the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) method will be used for allocation concealment. The envelopes will be opaque and numbered in sequence. After patient enrollment and

baseline data collection, the corresponding envelope will be opened by the researcher to determine the type of intervention. The individual responsible for generating the random allocation sequence will have no involvement in patient enrollment or outcome assessment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patients and the data analyst will be blinded to the type of intervention; however, blinding of the surgeon will not be feasible due to the nature of the surgical procedure. Patients will be informed that they may randomly receive one of the treatment methods, but they will ultimately remain unaware of the specific procedure performed. In addition, the statistician/data analyst will be blinded to group allocation. The treatment groups will be identified using specific codes (such as Group A and Group B), and the analyst will not have access to the actual type of interventions until completion of the statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

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Shahid Fahmideh Blvd, Hamadan

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6517838784

Approval date

2026-04-18, 1405/01/29

Ethics committee reference number

IR.UMSHA.REC.1405.015

Health conditions studied**1****Description of health condition studied**

scaphoid waist fracture

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Improvement in wrist joint function

Timepoint

At the beginning of the study and at 1-, 3-, and 6-month follow-up periods after surgery.

Method of measurement

MAYO questionnaire

2

Description

Pain severity

Timepoint

At the beginning of the study and at 1-, 3-, and 6-month follow-up periods after surgery.

Method of measurement

Visual Analogue Scale

3

Description

Wrist range of motion in flexion and extension

Timepoint

At 3 and 6 months after surgery.

Method of measurement

Joint range of motion in different directions using a goniometer.

4

Description

Fracture union rate.

Timepoint

At 1, 3, and 6 months after surgery.

Method of measurement

Based on the presence of tenderness in the anatomical snuffbox and the complete crossing of bony trabeculae on all three radiographic views (posteroanterior, lateral, and scaphoid views).

5

Description

Scapholunate angle on lateral radiographs.

Timepoint

At 1, 3, and 6 months after surgery.

Method of measurement

The angle between the scaphoid axis (a line drawn along its longitudinal poles) and the lunate axis (a line perpendicular to the line connecting its proximal and distal ends) is measured. The normal range is 30-60 degrees.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A 3-5 mm incision will be made on the volar or dorsal side. First, two pins will be inserted from distal to proximal and from volar to dorsal, or vice versa, toward the center of the scaphoid. Then, a screw will be inserted along the same axis, corresponding to the length of the inserted and measured pin, and fixation will be achieved. The postoperative cast will be removed after approximately one month.

Category

Treatment - Surgery

2

Description

Control group: A 3-5 mm incision will be made on the volar or dorsal side. First, two 1-mm pins will be inserted under C-arm guidance from the volar to dorsal direction or vice versa, and from distal to proximal. Then, one screw will be inserted from distal to proximal. After that, the pins will be removed and a cast will be applied. The cast will be removed one month after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Rohollah Abasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mohamad Amini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available